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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
08/737,633	11/15/1996	FABRIZIO SAMARITANI	P/42-60	5401
7590 09/24/2004			EXAMINER	
Edward A Meilman			LANDSMAN, ROBERT S	
Dickstein Shapi	rio Morin & Oshinsky LLP			
1177 Avenue of the Americas			ART UNIT	PAPER NUMBER
41st Floor			1647	
New York NY	10036-2714			

DATE MAILED: 09/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)
<b></b>	08/737,633	SAMARITANI ET AL.
Office Action Summary	Examiner	Art Unit
	Robert Landsman	1647
The MAILING DATE of this communication a Period for Reply	appears on the cover sheet wi	th the correspondence address
A SHORTENED STATUTORY PERIOD FOR REF THE MAILING DATE OF THIS COMMUNICATION  - Extensions of time may be available under the provisions of 37 CFR after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a real of the period for reply is specified above, the maximum statutory perion for reply within the set or extended period for reply will, by stated Any reply received by the Office later than three months after the material patent term adjustment. See 37 CFR 1.704(b).	N. 1.136(a). In no event, however, may a recept within the statutory minimum of thirt tod will apply and will expire SIX (6) MON tube, cause the application to become AB.	eply be timely filed y (30) days will be considered timely. THS from the mailing date of this communication
Status		
1) Responsive to communication(s) filed on 08	1 July 2004	
. —	his action is non-final.	
3) Since this application is in condition for allow		ers, prosecution as to the merits is
closed in accordance with the practice under	r <i>Ex parte Quayle</i> , 1935 C.D.	. 11, 453 O.G. 213.
Disposition of Claims	, ,	,
4)⊠ Claim(s) <u>1,3,4 and 6-15</u> is/are pending in the	annlication	
4a) Of the above claim(s) is/are withdr		
5) Claim(s) is/are allowed.	awn nom consideration.	
6)⊠ Claim(s) <u>1,3,7,9,10 and 14</u> is/are rejected.		
7) Claim(s) <u>4,5,8,11-13,15</u> is/are objected to.		
8) Claim(s) are subject to restriction and/	or election requirement.	
Application Papers		
9)☐ The specification is objected to by the Examin	ner	
10) The drawing(s) filed on is/are: a) ac	cented or h) objected to by	y the Evernines
Applicant may not request that any objection to the	e drawing(s) he held in abevance	o Soc 27 CED 1 85(a)
Replacement drawing sheet(s) including the correct	ction is required if the drawing/s	0. 000 07 CFR 1.00(a).
11) The oath or declaration is objected to by the E	Examiner. Note the attached (	7.5 95,00000 to. 000 07 OFK 1.121(d). Office Action or form PT∩-152
Priority under 35 U.S.C. § 119		- 1 - 102.
12) Acknowledgment is made of a claim for foreign	n priority undo- 25 U.S.O. O. A.	(40/-) (4) (6)
a) ☐ All b) ☐ Some * c) ☐ None of:	in priority under 35 U.S.C. § 1	19(a)-(d) or (f).
1. Certified copies of the priority documen	its have been received	
2. Certified copies of the priority documen	its have been received in Apr	alication No
3. Copies of the certified copies of the price	ority documents have been re	oncation INO
application from the International Burea	au (PCT Rule 17.2(a))	Solved in this Mational Stage
* See the attached detailed Office action for a list	t of the certified copies not re	ceived.
ttachment(s)		
Notice of References Cited (PTO-892)	4) T	(070 440)
Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/M	nmary (PTO-413) ⁄ail Date
Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date	)	mal Patent Application (PTO-152)
	6) 🔲 Other:	

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### **DETAEILD ACTION**

#### 1. Formal Matters

A. The Amendment dated 7/8/04 has been entered into the record.

B. Claims 1, 3, 4 and 6-15 are pending and are the subject of this Office Action.

C. All Statutes under 35 USC not found in this Office Action can be found, cited in full, in a

previous Office Action.

# 2. Claim Objections

A. The syntax of claim 7 could be improved by rewording the claim to clarify whether the "optional" albumin is human, or if human albumin is also added. The claim could be amended, for example, by reciting "wherein the albumin is present and is human."

# 3. Claim Rejections - 35 USC § 112, first paragraph - new matter

A. Claims 1, 3, 7, 9, 10 and 14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim recites "from about 0.6 to 24 MIU/ml." However, there is no support for (1) the term "about," nor is there support for the range "0.6 to 24 MIU/ml." It appears that the only range and concentration in the specification is "0.6 to 1 MIU/ml," "12 MIU/ml" and "24 MIU/ml." **This is a new matter rejection.** 

## 4. Conclusion

A. Claims 4, 6, 8, 11-13 and 15 are objected to, but would be allowable if rewritten in independent format to include all of the limitations of the base claims.

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## Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (571) 272-0888. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Brenda Brumback, can be reached on (571) 272-0961.

Official papers filed by fax should be directed to (703) 872-9306. Fax draft or informal communications with the examiner should be directed to (571) 273-0888.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-0700.

Robert Landsman, Ph.D. Patent Examiner Group 1600 September 21, 2004

ROBERT LAND